Vaccess™ PTA Balloon Dilatation Catheter

JAN - 9 2008

510(k) Summary

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc.
1625 West Third Street
P.O. Box 1740
Tempe, Arizona 85280
Phone: 480-303-2752
Fax: 480-449-2546
Contact: Jennifer Logvin, Regulatory Affairs Associate

2. Subject Device:

Device Trade Name:	Vaccess™ PTA Balloon Dilatation Catheter
Common or Usual Name:	Catheter, Angioplasty, Peripheral, Transluminal/ Catheter, Percutaneous
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

Device Trade Name:	Conquest™ PTA Balloon Dilatation Catheter
Cleared 510(K) Number:	K014212
Date of Cleared 510(K):	01/17/02

4. Summary of Change:

The modifications from the predicate device, the Conquest™ PTA Balloon Dilatation Catheter, to the subject device, the Vaccess™ PTA Balloon Dilatation Catheter, were to the balloon design, catheter design, and performance characteristics.

5. Device Description:

The Vaccess™ PTA Balloon Dilatation Catheter is a coaxial lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion of the guidewire and the second provides a channel for balloon inflation/deflation. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature.

6. Indications for Use of Device:

The Vaccess™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Vaccess™ PTA Balloon Dilatation Catheter, are substantially equivalent to those of the predicate device, the Conquest™ PTA Balloon Dilatation Catheter, in terms of intended use, indications for use, fundamental scientific technology, target population, operating principle, packaging configuration, sterility assurance level and method of sterilization.

8. Conclusions:

The Vaccess™ PTA Balloon Dilatation Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Vaccess™ PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device, the Conquest™ PTA Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Bard Peripheral Vascular, Inc.
c/o Ms. Jennifer Logvin
Regulatory Affairs Associate
1625 West Third Street
P.O. Box 1740
Tempe, Arizona 85280

Re: K073472
Trade/Device Name: Vaccess PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: LIT/DQY
Dated: December 10, 2007
Received: December 11, 2007

Dear Ms. Logvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073472

Device Name: Vaccess™ PTA Balloon Dilatation Catheter

Indications for Use: The Vaccess™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

Prescription Use X AND/OR Over-The-Counter Use
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073472